UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

OVIS ELLERBEE and JAMES ELLERBEE,

Plaintiffs,

v. Case No. 8:20-cv-1514-TPB-AEP

ETHICON, INC. and JOHNSON & JOHNSON,

Defendants.
_____/

ORDER GRANTING IN PART AND DENYING IN PART "DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS OF BRUCE ROSENZWEIG, M.D."

This matter is before the Court on "Defendants' Motion to Exclude Certain Opinions of Bruce Rosenzweig, M.D. and Brief in Support," filed on March 15, 2021. (Doc. 108). Plaintiffs responded in opposition on April 5, 2021. (Doc. 113). Upon review of the motion, response, court file, and record, the Court finds as follows:

Background

This case is one of thousands of similar cases filed since 2010.[1] Plaintiffs Ovis Ellerbee and James Ellerbee sued directly in the Southern District of West

[1] In the seven MDLs, over 100,000 cases have been filed, approximately 40,000 of which are in the Ethicon MDL. *See* MDL 2187 (C.R. Bard) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2187; MDL 2325 (American Medical Systems) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2325; MDL 2326 (Boston Scientific) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2326; MDL 2327 (Johnson & Johnson, Ethicon) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2327; MDL 2387 (Coloplast) Member List of Cases,

Virginia as part of the multidistrict litigation (MDL) entitled *In re: Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Lit.*, MDL No. 2327. The case was not resolved by the MDL transferee court ("MDL Court"), and on July 1, 2020, it was transferred to this Court.

On November 7, 2006, Ms. Ellerbee was implanted with Ethicon's TVT-O and Prolift devices at a hospital in Tampa, Florida. Both devices were designed and manufactured by Defendants Johnson & Johnson and Ethicon, Inc. In early 2017, Ms. Ellerbee's physician surgically removed what Plaintiffs claim to have been mesh located in the bladder mucosa. On February 23, 2017, Ms. Ellerbee underwent a revision/removal procedure and an anterior colporrhaphy. Ms. Ellerbee later had another mesh sling implanted.

On June 24, 2015, Plaintiffs sued directly in the MDL using a short-form complaint, alleging: Negligence (Count I), Strict Liability – Manufacturing Defect (Count II), Strict Liability – Failure to Warn (Count III), Strict Liability – Defective Product (Count IV), Strict Liability – Design Defect (Count V), Common Law Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX), Negligent Infliction of Emotional Distress (Count X), Breach of Express Warranty (Count XI), Breach of Implied Warranty (Count XII), Violation of Consumer Protection Laws (Count XIII), Gross Negligence (Count XIV), Unjust Enrichment (Count XV), Loss of Consortium (Count XVI),

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https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2387; MDL 2440 (Cook Medical) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2440; and MDL 2511 (Neomedic) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2511.

Punitive Damages (Count XVII), and Discovery Rule and Tolling (Count XVIII). On September 2, 2020, the Court granted in part, and denied in part, Defendants' motion for summary judgment, finding that Defendants were entitled to summary judgment on Counts I (in part), II, IV, VII, VIII, X, XI, XII, XIII, XIV (in part), XV, and XVI. (Doc. 85).

In the motion before this Court, Defendants raise various *Daubert* challenges to the proposed testimony of Bruce Rosenzweig, M.D. Dr. Rosenzweig has previously been qualified as an expert witness in pelvic mesh MDL litigation. *See*, *e.g.*, *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-4301, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014).

Legal Standard

An expert witness may testify in the form of an opinion if "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). "The party offering the expert testimony bears the burden of establishing, by a preponderance of the evidence, the expert's qualification, reliability, and helpfulness." *Payne v. C.R. Bard, Inc.*, 606 F. App'x 940, 942 (11th Cir. 2015) (citing *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc)).

Functioning as a gatekeeper, the district court plays an important role by ensuring that all scientific testimony is relevant and reliable. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W. Va. 2013). Although *Daubert* references specific factors for the district court to consider when evaluating relevancy and reliability, "[t]he inquiry to be undertaken by the district court is a flexible one focusing on the principles and methodology employed by the expert, not on the conclusions reached." *Id*. at 601-02 (internal quotations and citations omitted); *see Hanna v. Ward Mfg., Inc.*, 723 F. App'x 647, 649 (11th Cir. 2018) (outlining the criteria for the admissibility of expert witness testimony). Essentially, the Court is simply asked to determine if the evidence "rests on a reliable foundation and is relevant." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014) (quoting *Daubert*, 509 U.S. at 597).

Analysis

Plaintiffs designated Dr. Rosenzweig – a pelvic surgeon and urogynecologist – to offer general opinions involving Ethicon's TVT-O device, which is used to treat stress urinary incontinence ("SUI"). Here, Defendants make no argument that Dr. Rosenzweig is unqualified to serve as an expert. However, they seek to exclude his testimony, arguing that (1) Dr. Rosenzweig's opinions concerning non-synthetic mesh procedures as a safer alternative are irrelevant; (2) Dr. Rosenzweig's opinions criticizing the cut of TVT-O mesh are inconsistent with his prior opinions, unsupported by studies, and irrelevant; (3) Dr. Rosenzweig's opinions about the duties allegedly owed by a manufacturer are well outside of his expertise,

unreliable, and/or do not fit the facts of the case; and (4) Dr. Rosenzweig's opinions about certain complications and defects do not fit the facts of the case.

Opinions on Safer Alternatives to Defendants' Products

Defendants contend that Dr. Rosenzweig's opinions regarding safer alternatives to the TVT-O are irrelevant because he opines on safer alternative procedures rather than safer alternative designs. However, Dr. Rosenzweig's opinions that alternate medical procedures were safe and effective are relevant to demonstrating the product's inherent risks and assist the jury in appreciating the risk-utility analysis. *See, e.g.*, *Messina v. Ethicon, Inc.*, No. 6:20-cv-1170-Orl-40LRH, 2020 WL 7419586, at *4 (M.D. Fla. Dec. 17, 2020). The motion is denied as to this ground.

Opinions Criticizing Cut of TVT-O Mesh

Defendants argue that Dr. Rosenzweig's opinions criticizing the cut of TVT-O mesh should be excluded because his opinions in this case are inconsistent with his prior opinions, unsupported by studies, and irrelevant.

To the extent that Defendants believe Dr. Rosenzweig's opinions on the cut of the mesh differ from his opinions in other cases, such issue is ripe for cross-examination. His opinions are sufficiently supported and appear relevant to this case. The motion is denied as to these grounds.

Opinions on Duties Owed by a Manufacturer

Adverse Event Reporting

Defendants seek to exclude Dr. Rosenzweig's opinions about Ethicon's adverse event reporting. Plaintiffs agree that Dr. Rosenzweig will not offer the opinion that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading." As such, the Court will grant the motion to this extent. If Dr. Rosenzweig references particular adverse event reports to support other opinions, Defendants may object as appropriate at trial.

Physician Training

Defendants also seek to exclude Dr. Rosenzweig's opinions regarding the competency of other physicians. The MDL Court previously excluded proposed opinions regarding physician training and competency, concluding that these opinions were irrelevant. *See Wise v. C.R. Bard Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *13 (S.D.W. Va. Feb. 7, 2015) (citing *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-5762, 2014 WL 4851989, at *32 (S.D.W. Va. Sept. 29, 2014)). The Court sees no reason to depart from this reasoning. The motion is granted as to this request.

Complications and Defects

Defendants finally seek to exclude Dr. Rosenzweig's opinions about complications and defects that do not fit the facts of this case. However, evidence concerning risks and complications not experienced by Plaintiffs appear to be both

relevant and admissible as part of the risk-utility analysis and failure-to-warn claims. See *Wiltgen v. Ethicon, Inc.*, No. 12-cv-2400, 2017 WL 4467455, at *7 (N.D. Ill. Oct. 6, 2017); *Herrera-Nevarez by Springer v. Ethicon*, No. 17 C 3930, 2017 WL 3381718, at *6-8 (N.D. Ill. Aug. 6, 2017). The motion is denied as to this ground.

Accordingly, it is

ORDERED, **ADJUDGED**, and **DECREED**:

(1) "Defendants' Motion to Exclude Certain Opinions of Bruce Rosenzweig, M.D. and Brief in Support" (Doc. 108) is **GRANTED IN PART** and **DENIED IN PART**, as set forth herein.

DONE and **ORDERED** in Chambers, in Tampa, Florida, this 20th day of May, 2021.

TOM BARBER
UNITED STATES DISTRICT JUDGE